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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,670	01/18/2005	Hideji Tajima	10287.65	2325

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EXAMINER	
POPA, ILEANA	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
08/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,670	TAJIMA, HIDEJI	
	Examiner	Art Unit	
	ILEANA POPA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, and 4-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office action.

2. Claim 3 has been cancelled. Claims 1, 4-14, and 16 have been amended. Claims 19 and 20 are new.

Claims 1, 2, and 4-20 are pending and under examination.

Response to Arguments

Priority

3. Since all of the references applied in the Office Action mailed October 30, 2007, antedate the priority date of the foreign priority paper, the submission of an English translation of the foreign priority paper is currently not required.

Claim Rejections - 35 USC § 112, 2nd paragraph

4. The rejection of claims 4, 11, 16, and 17 are under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in response to Applicant's amendments to the claims filed on 04/30/2008.

Claim Rejections - 35 USC § 102

5. The rejection of claims 1-5, 9, and 13-17 under 35 U.S.C. 102(e) as being anticipated by Safir et al. (U.S. Patent No. 6,491,823) is withdrawn in response to Applicant's amendments to the claims filed on 04/30/2008.

Claim Rejections - 35 USC § 103

6. The rejection of claims 1-9, and 12-18 under 35 U.S.C. 103(a) as being unpatentable over Safir et al., in view of both Tajima et al. (U.S. Patent No. 5,702,950) and Ikeda et al. (U.S. patent No. 6,607,662) is withdrawn in response to Applicant's amendments to the claims filed on 04/30/2008.

7. The rejection of claims 1-5, 9, and 13-17 under 35 U.S.C. 103(a) as being unpatentable over Safir et al., in view of Deschamps et al. (Protein Expression and Purification, 1995, 6: 555-568) is withdrawn in response to Applicant's amendments to the claims filed on 04/30/2008.

New rejections

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 2, and 4-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Safir et al. (U.S. Patent No. 6,491,823, of record), in view of each Tajima et al. (U.S. Patent No. 5,702,950, of record), Ikeda et al. (U.S. patent No. 6,607,662, of record), and Deschamps et al. (Protein Expression and Purification, 1995, 6: 555-568, of record).

Safir et al. teach separation of polymers by using a carrier house/processing apparatus, wherein the apparatus comprises a chromatography column having a stationary phase and a drawing/discharging section comprising an auto-sampler connected to an injection valve having both inlet and outlet ports (i.e., fluid inlet/outlet), wherein the auto-sampler delivers fluid to the chromatographic column via the injection valve, i.e., a drawing/discharging section is configured to draw and discharge fluid through the inlet/outlet (claims 1 and 14) (column 8, lines 54-67, column 26, lines 3-25, column 27, lines 23-26, column 29, lines 8-11, column 34, lines 18-48 ands 59-67, column 35, lines 1-27). Safir et al. teach that the auto sampler can be programmed to automatically sample different polymers one after another to serially load the polymers into the system, i.e., the apparatus of Safir et al. comprises a transferring section for the transfer of the inlet/outlet with respect to containers provided outside, wherein the transferring section repeatedly draws and discharges a fluid with respect to the carrier housing (claim 1, 15, 16) (column 29, lines 50-67, column 30, lines 1-40). Safir et al. teach that the stationary phase comprises beads (i.e., particles), wherein the beads are made of silica (i.e., glass) or diverse polymers such as cross-linked resins and polystyrene (i.e., polymers that are able to be fixed or derivatized with a ligand) (claims

1, 4, 13, and 14) (column 41, lines 7-67, column 42, lines 1-30). Safir et al. also teach that a combination of carriers may be employed medium, such as a combination of carriers for size exclusion with carriers for adsorption chromatography, or reverse-phase chromatography carriers, i.e., Safir et al. teach a plurality of carriers that are a plurality of kinds (claim 5) (column 9, lines 7-15, column 37 bridging column 38). It is noted that the limitations of **(i)** the carrier not passing through the inlet/outlet (claims 1 and 4), **(ii)** the carrier being held in the housing section by self- weight and carrier holding sections at the bottom (claims 1, 9, and 14), **(iii)** the carrier housing section having a large diameter enabling the carrier to pass through (claims 2 and 17), or **(iv)** the inlet/outlet having a smaller diameter enabling insertion into containers provided outside (claim 2) are all inherent to any chromatographic column. Safir et al. do not teach a detachable nozzle (claims 1 and 14). However, one of skill in the art would have known to use such detachable nozzles or connectors for easy coupling of tubing with different dimensions, as needed. With respect to the diverse carriers recited in claims 4 and 8, it is noted that, although Safir et al. do not specifically disclose them, they do teach the use of diverse carriers such as beads, rods, monolithic carriers, or other shaped particles, wherein each carrier can be optimized fore a particular separation with respect to the material, size, shape, or pore size (column 35, lines 3-12). Therefore, one of skill in the art would have known to use practically any type of carrier, including the claimed ones. With respect to the limitations recited in claims 6 and 7, one of skill in the art would have known to use the claimed adhesion prevention sections when needed. With respect to

the limitation recited in claim 18, one of skill in the art would have known to remove the carrier when needed.

Safir et al. do not teach a carrier comprising a magnetic substance, wherein the carrier is held in the housing section by a magnetic field applied from outside (claim 12). However, at the time the invention was made, the prior art taught the use of magnetic particles in association with external magnetic fields in chromatographic separations, wherein the magnetic beads are held in the chromatographic column by the magnetic field (see for example Tajima et al., Abstract, column 3, lines 33-67; Ikeda et al., Abstract, column 8, lines 5-67, column 9, lines 1-19). It would have been obvious to one of skill in the art, at the time the invention was made to substitute the beads of Safir et al. with the combination of magnetic beads/magnetic field taught by the above cited art to achieve the predictable result of holding the carrier in the carrier housing.

Safir et al. do not teach a translucent carrier housing and an outside apparatus that measures luminescence on the carrier (claim 10). However, at the time the invention was made, Deschamps et al. taught monitoring GFP chromatographic purification by using a translucent column and measuring GFP luminescence under black light (p. 556, columns 1 and 2). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the apparatus of Safir et al., by replacing their column with the column of Deschamps et al., with a reasonable expectation of success. One of skill in the art would have been motivated to do so in order to monitor the chromatographic purification of luminescent compounds, such as GFP. One of skill in the art would have been expected to have a reasonable

expectation of success in making using such because the art teaches that such columns can be successfully used to follow GFP purification. With respect to the limitation of the carrier housing section having a side face made in a plane (claim 11), one of skill in the art would know to modify the carrier housing section according to the measuring equipment used. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

Applicant's arguments are answered below to the extent that they pertain to the instant rejection.

With respect to claim 1, Applicant argues that, although Safir et al. disclose an auto sampler which can be programmed to automatically sample different polymers one after another to serially load the polymers, they not disclose a transferring section which transfers the chromatographic column, and therefore, since the chromatographic column is characterized by the Examiner to be the carrier housing section recited in claim 1, it is clear that Safir et al. do not disclose a transferring section which transfers said carrier housing section including said inlet/outlet relatively with respect to containers provided outside, as required by amended claim 1. With respect to claim 14, Applicant argues that Safir et al. do not disclose a carrier housing section comprising an opening having a size enabling a carrier to pass through and said carrier being formed in a size capable of passing through said opening but not capable of passing through said inlet/outlet.

Applicant's arguments are acknowledged but not found persuasive. As written, claim 1 does not require that the carrier housing itself be moved. The claim requires only that the housing with its inlet/outlet be transferred with respect to outside containers. Since Safir et al. teach that their auto sampler automatically loads different polymers located in different outside containers to serially load the polymers into the system, the housing with its inlet/outlet is transferred with respect to outlet containers. The limitations of the carrier housing having an opening with a size enabling a carrier to pass through and of the carrier being formed in a size capable of passing through said opening but not capable of passing through said inlet/outlet are inherent to the chromatography column and carrier of Safir et al. Their chromatographic column which is loaded with a solid carrier must have an opening enabling the carrier to be loaded into the column and the carrier is not able to pass through their injecting valve (i.e., inlet/outlet).

10. Claims 1, 2, 4, 5, 8, 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tajima (U.S. Patent No. 5,895,631).

Tajima teaches a pipette device comprising a drawing/discharging section having a nozzle which connects to a detachable cylinder chip having an inlet/outlet, wherein the cylinder chip is loaded with magnetic particles coupled to biotin or streptavidin (i.e., a carrier housing), wherein the drawing/discharging section draws fluid into the cylinder chip via the inlet/outlet and discharges the fluid out of the cylinder chip via the same inlet/outlet; the magnetic particles are held in a predetermined position due to a

magnetic field and the cylinder chip comprises a small diameter section in contact with the fluid to be drawn, an intermediate diameter section which captures the magnetic particles, and a large diameter section (i.e., opening) detachably connected to the nozzle (claims 1, 2, 12, 14, 19, and 20) (column 3, lines 50-67, column 4, lines 59-67, column 5, lines 14-22, column 6, lines 17-67, column 7, lines 7-27, 65, and 67, column 8, lines 1-7, Fig. 7, claims 1, 3-5, and 9). Tajima teaches that the pipette device has a transferring section capable of transferring the carrier housing with respect to outside containers comprising different reagents (claims 1, 15, and 16) (column 7, lines 37-48, column 8, lines 8-67). Tajima also teaches that the detachable chips can further contain filter tips, wherein the filter tips can contain silica filters (i.e., porous glass) (claims 5, 8, and 13) (column 4, lines 22-37, column 9, lines 33-40, column 13, lines 54-58, Fig. 7 and 13). Tajima et al. do not teach their magnetic particles having a size such that they are not capable to pass through the inlet/outlet (claims 1, 4, 14, 17), nor do they teach their large diameter section as comprising a filter (claims 19 and 20). However, one of skill in the art would know to provide the large diameter section with a filter; one of skill in the art would be motivated to so in order to avoid contaminating the pipette nozzle. With respect to the magnetic particles not being able to pass through the inlet-outlet, one of skill in the art would be motivated to do such in order to avoid loss of magnetic beads (and therefore, loss of captured material). It is noted that by doing such, one of skill in the art would necessarily remove the carrier through the large diameter section (claim 18). Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD

/Joseph T. Woitach/

Supervisory Patent Examiner, Art Unit 1633